UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION	MDL No. 15-2642
This Document Relates to All Cases	Master Docket Case No. 0:15-md-02642 Hon. Judge John R. Tunheim **FILED UNDER SEAL**

PLAINTIFFS' MASTER COMPLAINT

Pursuant to Pretrial Order No. 3[1], Plaintiffs, by and through counsel, file this Master Complaint against Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Corporation, Bayer AG, Merck & Co., Inc. (collectively referred to as the "Bayer Defendants"), Johnson & Johnson, Janssen Research & Development, LLC, Janssen Pharmaceuticals, Inc. (collectively referred to as the "J&J Defendants), and McKesson Corporation as follows:

INTRODUCTION

1. This case involves the prescription drugs Cipro® (ciprofloxacin), Avelox® (moxifloxacin), and Levaquin® (levofloxacin) (collectively referred to hereafter as "FLQs").

[1] Pursuant to Pretrial Order No. 3, attached hereto is a Short Form Complaint to be utilized by individual Plaintiffs in this MDL.

2. Cipro and Avelox are designed, developed, manufactured, tested, packaged, promoted, marketed, advertised, distributed, labeled, and/or sold by the Bayer Defendants.

3. Levaquin is designed, developed, manufactured, tested, packaged, promoted, marketed, advertised, distributed, labeled, and/or sold by the J&J Defendants.

4. Collectively, the Bayer Defendants and J&J Defendants are referred to herein as "Defendants."

5. Plaintiffs maintain that Cipro, Avelox and Levaquin are defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce to treat infections for which they were not required, and lacked proper warnings and directions as to the dangers associated with their all of their uses.

PARTIES

6. Plaintiffs are individuals who reside in various states and/or territories in the United States and bring claims for personal and economic injuries sustained by the use of the Defendants' FLQs, including Cipro, Avelox, and Levaquin. By reason of the foregoing acts and omissions and as a direct and proximate result of being prescribed and ingesting Defendants' FLQs, Plaintiffs sustained personal injuries (for some, wrongful death), including irreversible peripheral neuropathy which is lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, physical impairment, expenses for hospitalization and medical treatment, and loss of earnings, among other damages.

7. Defendant Bayer HealthCare Pharmaceuticals, Inc. ("Bayer Healthcare") is a Delaware corporation that has its principal place of business at 100 Bayer Boulevard, in Whippany, New Jersey 07981.

8. In January 2008, Bayer Pharmaceuticals Corporation was merged into Bayer Healthcare.

9. Bayer Healthcare is involved in the labeling, supplying, selling, and distribution of pharmaceutical products, including Cipro and Avelox, in the United States.

10. Defendant Bayer Corporation ("Bayer Corp.") is an Indiana corporation that has its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

11. Bayer Corp. (formerly known as Miles, Inc.) is an American subsidiary of a German parent, Bayer AG.

12. Bayer Corp. was engaged in the business of testing, manufacturing, distributing, marketing, advertising, labeling, and selling Cipro and Avelox in the United States.

13. Bayer AG ("Bayer AG") is a German company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

14. Bayer AG is one of the largest pharmaceutical companies in the world and is the researcher, producer, and manufacturer of Cipro and Avelox.

15. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation that has its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

16. Merck has promoted Avelox in the United States since its acquisition of Schering-Plough Corporation on November 4, 2009.

17. At all times material hereto, Merck was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avelox.

18. Defendant Johnson & Johnson ("J&J") is a fictitious name adopted by Johnson & Johnson, a New Jersey corporation that has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

19. J&J, and its "Family of Companies," is involved in the research, development, sales, and marketing of pharmaceutical products, including Levaquin.

20. Defendant Janssen Research & Development, LLC ("Janssen R&D" and formerly known as Johnson & Johnson Pharmaceutical Research & Development, LLC) is a limited liability company organized under the laws of the State of New Jersey, with its principal place of business at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

21. The members of Janssen R&D are corporate citizens of Pennsylvania, New Jersey and Delaware. Accordingly, Janssen R&D is a citizen of Pennsylvania, New Jersey and Delaware for purposes of determining diversity under 28 U.S.C. § 1332.

22. At all times material hereto, Janssen R&D conducted research, development, and testing on Levaquin.

23. Janssen R&D is part of the J&J "Family of Companies."

24. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharma" and formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc.) is a Pennsylvania corporation that has its principal place of business at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.

25. At all times material hereto, Janssen Pharma was the responsible U.S. entity for the design, manufacture, labeling, distribution, marketing, and sale of the drug Levaquin in the United States.

26. Defendant Janssen Pharma is a wholly owned subsidiary of J&J.

27. Defendant McKesson Corporation (hereinafter "McKesson") is a Delaware corporation with its principal place of business at One Post Street, San Francisco, California 94101. At all relevant times, McKesson was in the business of packaging, re-packaging and/or distributing Levaquin, Avelox and Cipro throughout the United States.

28. McKesson touts itself as, among other things: (1) the largest pharmaceutical distributor in North America distributing one-third of the medications used daily in North America, (2) the nation's leading health care information technology company, and (3) a provider of "decision support" software to help physicians determine the best possible clinical diagnosis and treatment plans for patients.

29. At all times herein mentioned, McKesson was among the largest distributors of Defendants' pharmaceutical products, including Defendants' FLQ drugs.

30. At all times herein mentioned, McKesson provided research services to pharmaceutical companies such as Defendants. For example, on its website, McKesson offered "bio-pharmaceutical manufacturers an unsurpassed suite of services to accelerate the approval and successful commercialization of specialty pharmaceuticals across the product life cycle." Through its Risk Evaluation and Mitigation Strategies (REMS) Services, McKesson provided pharmaceutical manufacturers like Defendants with a wide range of risk-based services, including consultation on FDA submissions, strategic program designs, data management, and assistance with drug launch.

31. Upon information and belief, McKesson distributed the FLQ drugs that certain Plaintiffs ingested, resulting in the injuries claimed herein.

32. Defendants are authorized to do business in the United States and derive income from doing business in the United States.

33. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities within the United States, thus invoking the benefits and protections of its laws.

34. Upon information and belief, the Bayer Defendants did act together to design, sell, advertise, manufacture and/or distribute Cipro and Avelox with full knowledge of its dangerous and defective nature.

35. Upon information and belief, the J&J Defendants did act together to design, sell, advertise, manufacture and/or distribute Levaquin with full knowledge of its dangerous and defective nature.

JURISDICTION AND VENUE

36. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiffs and Defendants.

37. Defendants have significant contacts in the vicinage of Plaintiffs' residence such that they are subject to the personal jurisdiction of the court in that vicinage.

38. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the vicinage of Plaintiffs' residences, as well as in this district. Pursuant to 28 U.S.C. § 1391(a), venue is proper in both districts.

39. Pursuant to the Transfer Order of the Judicial Panel on Multidistrict Litigation, *In re Fluoroquinolone Products Liability Litigation*, 122 F.Supp.3d 1378 (J.P.M.L. August 17, 2015), venue is also proper in this jurisdiction pursuant to 28 U.S.C. § 1407.

FACTUAL ALLEGATIONS

40. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the FLQ drugs Cipro, Avelox, and Levaquin.

41. Plaintiffs were prescribed and/or otherwise lawfully obtained Cipro, Avelox, and Levaquin. Thereafter, Plaintiffs suffered irreversible peripheral neuropathy, or symptoms of irreversible peripheral neuropathy, and/or a worsening of those

symptoms, including pain, burning, tingling, numbness, weakness, alterations of sensation, and/or experienced symptoms of irreversible peripheral neuropathy in addition to injuries from the following body systems: musculoskeletal, neuropsychiatric, sensory (e.g., vision or hearing), skin, and cardiovascular.

42. FLQs are broad-spectrum synthetic antibacterial agents marketed and sold in oral tablet, IV solution, and ophthalmic solution, used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria. They are members of the quinolone class of antibiotics.

43. Quinolones are divided into four generations based on their spectrum of antimicrobial activity. The 1st generation, non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

44. Twenty years later, in the early 1980s, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called 2nd generation quinolones included Noroxin® (norfloxacin), Cipro, Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

45. Cipro was approved by the United States Food and Drug Administration ("FDA") in October 1987 for use in the United States, and is the brand name for the antibiotic ciprofloxacin. Since its introduction to the market in the United States in 1987, the Bayer Defendants have derived over $1 billion in U.S. net sales of all Cipro products. Cipro went off patent on December 9, 2003.

46. Fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the United States market due to unacceptable risks of certain adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992 only six months after approval due to low blood sugar, kidney failure, and a rare form of anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT-interval prolongation; Zagam® (sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in May 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

47. Avelox was approved by the FDA on December 10, 1999 for use in the United States, and is the brand name for the antibiotic moxifloxacin.

48. With the patent for Cipro (another blockbuster fluoroquinolone) set to expire in December 2003, the Bayer Defendants set out to develop and effectively market Avelox in order to be more competitive with 3rd and 4th generation fluoroquinolones, including Levaquin. Avelox quickly became the Bayer Defendants' heir apparent and successor to Cipro.

49. Similar to Cipro, Avelox has proven to be a blockbuster drug for the Bayer Defendants. In 2007 alone, Avelox generated international sales of $697.3 million dollars.

50. Defendant Bayer Healthcare has indicated on its website that Avelox is "safe and effective" and "has a well-characterized safety profile, which has been studied in over 14,000 patients in clinical trials and 92,000 patients in post marketing surveillance studies."

51. However, the scientific evidence has established a clear association between Cipro and Avelox and an increased risk of long-term and sometimes irreversible peripheral neuropathy.

52. Levaquin was approved by the FDA on December 20, 1996 for use in the United States, and is the brand name for the antibiotic levofloxacin.

53. In 2003, after generic versions of Cipro went on the market, one of the J&J Defendants "key strategies" was to "displace ciprofloxacin" as the leading fluoroquinolone on the market. Levaquin subsequently became the number one prescribed fluoroquinolone in the United States. Indeed, by the end of 2004 Levaquin had "surpassed $1 billion in net trade sales."

54. In 2006, after generic versions of Zithromax, a highly popular macrolide antibiotic, went on the market, Levaquin became the number one prescribed antibiotic in the world.

55. In 2007, Levaquin was ranked 37th of the top 200 drugs that were prescribed in the United States.

56. In 2007, Levaquin was ranked 19th in world sales of prescribed drugs.

57. In 2007, Levaquin accounted for 6.5% of J&J's total revenue, generating $1.6 billion in revenue, an 8% increase over the previous year.

58. Defendant Janssen Pharma indicates on its website that "[i]n a large number of clinical trials, Levaquin has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections."

59. However, the scientific evidence has established a clear association between Levaquin and an increased risk of long-term and sometimes irreversible peripheral neuropathy, no matter whether the FLQs are stopped once symptoms develop.

60. Prior to applying to the FDA for and obtaining approval of their FLQs, Defendants knew or should have known that consumption of FLQs were associated with and/or would cause chronic and/or permanent peripheral neuropathy.

61. By 1988, Defendants possessed at least one published case report (funded in part by Bayer),[2] which Defendants knew or should have known constituted a safety "signal" that the use of FLQs was associated with "peripheral paraesthesia" (a form of peripheral nerve damage) and required further investigation and study.

62. Defendants failed to appropriately and adequately inform and warn Plaintiffs and Plaintiffs' prescribing physicians of the serious and dangerous risks associated with the use of FLQs concerning irreversible peripheral neuropathy, as well as other severe and personal injuries, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish, physical impairment, diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.

[2] *See* Therapy of acute and chronic gram-negative osteomyelitis with ciprofloxacin. Report from a Swedish Study Group (Karlman, K. et al.). *J Antimicrob Chemother* 1988 Aug;22(2):221-8.

63. The warning labels for Levaquin and Cipro from September 2004 through August 2013 and Avelox from August 2012 through August 2013 misled and deceived Plaintiffs and their treating physicians by incorrectly advising them that peripheral neuropathy associated with FLQs was "rare" and in any case could be avoided by discontinuing the drug upon the onset of certain symptoms. The truth, however, is that the onset of irreversible peripheral neuropathy is often rapid and discontinuation of the drug will not ensure that the peripheral neuropathy is reversible. Defendants misled patients and physicians by omitting any mention of the possibility that FLQ use could result in irreversible peripheral neuropathy.

64. The warning label for Avelox from September 2004 through July 2012 misled and deceived Plaintiffs and their treating physicians by incorrectly advising them that peripheral neuropathy associated with FLQs was "rare." The Avelox label during this time period also omitted any mention of the possibility that FLQ use could result in irreversible peripheral neuropathy.

65. Further, though this injury can be severe and debilitating, the language regarding the "rare" risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Defendants' FLQ labels; the language was in no way highlighted for the benefit of prescribing physicians and patients.

66. Additionally, upon information and belief, following the 2004 label change Defendants did not issue any "Dear Doctor" or "Dear Healthcare Professional" letters in the United States that were specific to Cipro, Avelox, or Levaquin and the risk of developing irreversible peripheral neuropathy. Further, Defendants failed to disclose the

serious and dangerous side effect of irreversible peripheral neuropathy when promoting Cipro, Avelox and Levaquin to physicians.

67. Despite their knowledge that their FLQ drugs were associated with an elevated risk of prolonged and/or permanent peripheral neuropathy, Defendants' promotional campaign was focused on the purported "safety profile" of their FLQs.

68. FDA regulations require that manufacturers monitor and report adverse events ("AEs") associated with their marketed products. 21 C.F.R. § 314.80; 21 C.F.R. § 314.81. The manufacturers are required to review all adverse experience information pertaining to their products obtained from any source, foreign or domestic, including from commercial marketing experience, postmarketing clinical investigations, post-marketing epidemiological/surveillance studies, reports in the scientific literature and unpublished scientific papers. Manufacturers review this information for safety "signals."

69. The FDA has recognized that case reports and case series can play important roles in serving as "safety signals." In fact, the FDA states that a single, well-documented case report can be viewed as a safety signal, particularly if the report describes a positive rechallenge.[3]

70. Indeed, even a single case report may be sufficient to establish a *causal* relationship between the use of a product and an adverse event.[4]

[3] *See* U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Good Pharmacovigilence Practices and Pharmacoepidemiologic Assessment (2005).

[4] *See* Principles & Practice of Public Health Surveillance, at p. 343. Steven M. Teutsch & R. Elliott Churchill, eds. Third Edition, Oxford University Press, 2010.

71. In the pharmaceutical industry, including within Defendants' companies, safety signals generally indicate the need for further investigation.[5]

72. After a signal is identified, the Bayer Defendants and J&J Defendants are obligated to further assess the signal to determine whether it represents a potential safety risk that should be included in product labeling.

73. The J&J Defendants claim to "continually collect and monitor information on the safety and effectiveness of all our medicines, and, in cooperation with the U.S. FDA and other health authorities, we incorporate new data into our product labels so doctors and patients can make informed decisions."[6]

74. The Bayer Defendants likewise claim that "[w]e maintain accurate product labels that share information about the benefits and risks associated with fluoroquinolone use, and report all adverse events we learn about to the FDA."[7]

75. Despite these representations, as early as 1988 there was evidence in the medical literature of peripheral nerve damage associated with FLQ therapy (ciprofloxacin), representing a safety "signal" that the Bayer Defendants and J&J Defendants ignored in violation of the federal regulations.[8] Specifically, in a report from a Swedish Study Group, funded in part by Bayer, Karlman et al. reviewed 40 patients

---

[5] *See* Guidance for Industry: Good Pharmacovigilence Practices and Pharmacoepidemiologic Assessment (2005).

[6] https://www.washingtonpost.com/national/health-science/it-pays-to-read-the-warnings-when-you-open-up-a-prescription/2015/08/03/a29e11b4-d70e-11e4-b3f2-607bd612aeac_story.html.

[7] https://www.washingtonpost.com/national/health-science/it-pays-to-read-the-warnings-when-you-open-up-a-prescription/2015/08/03/a29e11b4-d70e-11e4-b3f2-607bd612aeac_story.html.

[8] *See* 21 C.F.R. 201.57(e) (product label must be revised as soon as there was reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved).

treated with ciprofloxacin for acute or chronic osteomyelitis (38) and acute arthritis (2). The authors identified 9 patients with adverse experiences. Of these 9 adverse experiences, the authors reported one case of "peripheral paraesthesia" which they found was "probably related" to ciprofloxacin treatment.[9]

76. Thereafter, a 1990 study by Chan et al. reviewed 27 patients treated with the fluoroquinolone Peflox for urinary tract infections.[10] One patient developed peripheral neuropathy that resolved 4 weeks after discontinuation, generating an incidence rate of 3.7%. The authors concluded that "[i]ts [i.e. peripheral neuropathy's] relation to the use of pefloxacin was *indisputable*, since it recurred on re-introduction of the drug." (emphasis added). Reviewers at the FDA's Office of Surveillance and Epidemiology (OSE) concluded in an April 17, 2013 pharmacovigilence review that this case represents a positive dechallenge.

77. Then, in 1992, Aoun et al. published a case report titled "Peripheral neuropathy associated with fluoroquinolones."[11] Specifically, the authors reported an association between the use of pefloxacin, ofloxacin and ciprofloxacin and peripheral neuropathy in a 37 year old patient. The case report was notable for numerous positive dechallenges and rechallenges of the fluoroquinolones in the patient, resulting in reviewers at FDA's OSE to characterize the quality of the evidence reported as a "strong

[9] *See* Karlman, K. et al. (Report from a Swedish Study Group). Therapy of acute and chronic gram-negative osteomyelitis with ciprofloxacin. *J Antimicrob Chemother* 1988 Aug;22(2):221-8.
[10] Chan, PC et al., Clinical experience with pefloxacin in patient with urinary tract infections, *Br. J. Clin. Pract.* 1990.
[11] Auon, M. et al. Peripheral neuropathy associated with fluoroquinolones. Letter to Editor. *Lancet*. 1992.

case." Indeed, the J&J Defendants have acknowledged in other causality assessments that a "positive rechallenge makes causality of levofloxacin highly probable."

78. In 1996, Hedenmalm et al. reported the results from a review of 37 patients treated with fluoroquinolones.[12] Of those, 81% experienced paresthesia, 51% experienced numbness, 27% experienced pain, and 11% experienced muscle weakness. The highest incidence of reported symptoms occurred during the first weeks of treatment. The duration of symptoms in the cases where information was provided varied from a few hours to over a year. According to reviewers at FDA's OSE, the quality of evidence from at least 20 of the 37 cases seemed to be "strong with both a good temporal relationship and a positive dechallenge."

79. One of the first large scale studies in the United States that included the post market experience concerning fluoroquinolones and neuropathy was "Peripheral Neuropathy Associated with Fluoroquinolones" written by Jay S. Cohen. The Cohen paper was published in December 2001 and revealed that adverse events reported by 45 patients suggested a possible association between fluoroquinolones and long-term peripheral nervous system damage. The study noted in particular the presence of severe and/or persistent nerve problems. Over one-half of the patients surveyed said their symptoms lasted for more than a year, and eighty percent characterized their symptoms as severe. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy. The study concluded with the

[12] Hedenmalm, K. et al. Peripheral sensory disturbances related to treatment of fluoroquinolones. *J. Antimicrob. Chemother*. 1996;37:831-7.

following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs' product information."

80. Beyond the numerous safety signals generated by internal postmarketing review and the medical literature, Defendants were also put on notice of an association between fluoroquinolone use and peripheral neuropathy by the FDA, in 2001 and again in 2003.

81. In 2001, the Division of Drug Risk Evaluation within the Office of Drug Safety uncovered 35 reports of quinolone-associated peripheral neuropathy and 46 cases of potentially prolonged paresthesia collected by the FDA's Adverse Event Reporting System ("AERS") for the quinolone class (including reports for ciprofloxacin, ofloxacin, and levofloxacin). Twenty-eight of these cases lasted over one month, with some patients still experiencing symptoms two years after fluoroquinolone use.

82. In 2003, FDA's Office of Drug Safety conducted an additional post-marketing safety review of the AEs reported in the FDA's AERS for those who had been treated with ciprofloxacin (Cipro), ofloxacin (Floxin), and/or levofloxacin (Levaquin). The AERS contained 108 unduplicated cases reported as peripheral neuropathy, or events suggestive of peripheral neuropathy, lasting at least one month in patients who had been treated with ciprofloxacin, ofloxacin and/or levofloxacin. As noted in the FDA's Office of Drug Safety review report dated June 10, 2003, the cases were temporally associated with fluoroquinolones, with a median time to onset of a few days. Gender distribution was approximately equal. The report further stated that these cases provided an indication

that the fluoroquinolones could have been responsible for the prolonged peripheral neuropathies. As a result of its review, the Office of Drug Safety recommended that "peripheral neuropathy" be added to the labeling for ciprofloxacin and levofloxacin as it had been for ofloxacin.

83. In September 2004, Defendants amended the labeling for Cipro (ciprofloxacin) and Levaquin (levofloxacin). The amended label contained the following statement in the Warnings section:

> **Peripheral Neuropathy:** Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation in order to prevent the development of an irreversible condition.

84. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that Defendants' existing warnings regarding peripheral neuropathy were inadequate. On August 15, 2013, an updated warning and accompanying safety communication was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included in the labels for all fluoroquinolones, including Cipro, Avelox and Levaquin. The updated warning also removed the statement that peripheral neuropathy occurred only in "rare" cases:

> Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including [drug name].

> Symptoms may occur soon after initiation of [drug name] and may be irreversible. [Drug name] should be discontinued immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.

85. Notwithstanding this 2013 label change, however, the labeling for Levaquin remains inadequate and confusing regarding the risk of developing irreversible peripheral neuropathy following the use of Levaquin.

86. For instance, the Levaquin label currently states under the "Warnings and Precautions" section of the first page as follows: "Peripheral neuropathy: discontinue immediately if symptoms occur in order to *prevent irreversibility* (5.8)." This statement implies to physicians and patients that, if the patient stops using the drug immediately after symptoms occur, the symptoms are reversible. However, in section 5.8, the label states that "Symptoms [of peripheral neuropathy] may occur soon after initiation of LEVAQUIN® and *may be irreversible*." This later statement conflicts with the earlier statement by implying that no matter whether the patient stops using the drug immediately after experiencing symptoms, the symptoms may be permanent. It is inconsistent to advise physicians and patients in one section of the label that that the symptoms of peripheral neuropathy are reversible if the drug is stopped immediately after symptoms occur, but to advise physicians and patients in another section of the label that symptoms may be irreversible no matter whether they stop taking the medication immediately upon experiencing symptoms.

87. Additionally, Defendants' updated label does not disclose the serious, progressive and disabling nature of FLQ-induced irreversible peripheral neuropathy.

88. Upon information and belief, Defendants failed to provide adequate information to the medical community about the frequency with which AEs indicative of peripheral neuropathy were being reported. Prior to the August 2013 label change, Defendants knew or should have known that FLQ-associated neuropathies could be rapid, permanent, and disabling, and that such injuries were not, as they had been stating, "rare." For instance, from September 2004 through August 2013, the FLQ labels stated that "Rare cases of polyneuropathy affecting small and/or large axons resulting in *paresthesias*, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones" (emphasis added). The pre-2013 FLQ labels further represented that "the most common adverse drug reactions (≥3%) are nausea, headache, diarrhea, insomnia, constipation, and dizziness."

89. Even though the J&J Defendants represented, through their labeling, to patients and the medical community that central nervous system AEs such as *paresthesias* were "rare" and were not a common adverse drug reaction, J&J knew the opposite to be true.[13] As early as the mid-1990s, the J&J Defendants knew from their own postmarketing experience that the "most frequently reported" central nervous system AEs in the United States from December 1996 through August 1999 were "dizziness, *paraesthesia* and headache" (emphasis added). The J&J Defendants knew that the same was true outside the United States, but for an even longer reporting period. The J&J Defendants knew from non-U.S. postmarketing experience that "most frequently

[13] "Paraesthesia" is an abnormal sensation, typically tingling or prickling ("pins and needles"), burning, or numbness, caused primarily by damage to peripheral nerves.

reported" central nervous system AEs outside the United States from December 1993 through August 1999 were "dizziness, *paraesthesia* and headache" (emphasis added). Yet the J&J Defendants deliberately avoided listing "paraesthesia" in their marketing statements and product labels as one of the most common adverse drug reactions. Upon information and belief, the trend of symptoms indicative of peripheral neuropathy (including pain, burning, tingling, numbness, weakness, and/or alterations of sensation) continued to be one of the most frequently reported central nervous system AEs for all Defendants from the 1990s through the labeling change in August 2013.

90. Defendants' failure to adequately warn physicians resulted in: (1) patients receiving FLQs instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which patients presented to the provider; and (2) physicians failing to warn and instruct consumers about the risk of long-term peripheral nervous system injuries associated with FLQs.

91. The failure of Defendants to include appropriate warnings in their products' labels as published to the medical community also resulted in an absence of adequate warnings in patient information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.

92. Despite Defendants' knowledge and failure to adequately warn Plaintiffs and their physicians of the above, Defendants continued to market their FLQs as a first-line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections—conditions for which many safer antibiotics were and are available.

93. In January of 2014, Ayad Ali published "Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis," which reemphasized the link between fluoroquinolones and peripheral neuropathy and called for increased scrutiny of the risk-benefit of fluoroquinolone prescriptions.

94. An epidemiologic study published in the August 2014 online edition of *Neurology* provided further quantitative support for the association between fluoroquinolone antibiotics and peripheral neuropathy.[14] The study compared 6,226 cases of peripheral neuropathy among men ages 48-80 to 24,904 controls and determined that those on fluoroquinolones were at a statistically significant higher risk of developing peripheral neuropathy (RR = 1.83, 95% CI: 1.49-2.27), with current users having the highest risk of exposure (RR = 2.07, 95% CI: 1:56-2.74).

95. Notably, long before the publications from Ali et al. and Etminan et al., the J&J Defendants acknowledged that a causal relationship existed regarding FLQs and peripheral neuropathy. Specifically, following the FDA's October 2003 request for a label change regarding FLQs and peripheral neuropathy, the J&J Defendants conducted an internal evaluation of the proposed labeling change. This evaluation led them to conclude in an internal document dated December 2003 that there were case reports "across the quinolone class" of signs and symptoms "consistent with peripheral neuropathy." This assessment further concluded that "onset may be rapid" and "[r]eports

[14] Etminan M, Brophy JM, Samii A. Oral fluoroquinolone use and risk of peripheral neuropathy: A pharmacoepidemiologic study. *Neurology* 2014; Epub 2014 Aug 22.

were consistent with a causal association for both levofloxacin and oxfloxacin. Some reports include positive dechallenge and/or rechallenge." The report further acknowledged that symptoms of peripheral neuropathy "can occur in setting of other signs and symptoms (allergy, musculoskeletal, and CNS)."

96. On November 5, 2015, the FDA held a joint meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss the safety and efficacy of systemic fluoroquinolones in the context of three indications: acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis in those with chronic obstructive pulmonary disease (ABECB-COPD), and uncomplicated urinary tract infections (uUTI). The FDA asked committee members to determine whether the benefits of FLQ therapy in these three indications justifies the associated risks of FLQ use.

97. While fluoroquinolones are currently approved for these three indications, FDA reviewers, along with over 30 open public hearing speakers, voiced the need for stronger labels on these indications due to the modest or absent treatment benefits of the drugs for the three indications, and the serious adverse events associated with their use. These serious adverse events include tendonitis, tendon rupture, central nervous system effects, peripheral neuropathy, myasthenia gravis exacerbation, phototoxicity, hypersensitivity and certain cardiovascular effects (i.e., QT prolongation).

98. In advance of the advisory committee meeting, FDA reviewers released briefing documents that indicated the potential side effects of fluoroquinolone use, including permanent peripheral neuropathy, may outweigh the benefits provided by the

medications, as patients often receive the drugs for infections that resolve themselves or can be treated with medications that do not carry the same risks. For instance, an evaluation of placebo-controlled trials in ABS or mild ABECB-COPD showed that a large proportion of patients randomized to receive placebo recovered and thus the illnesses appeared to be self-limited for many. Moreover, some trials failed to show any differences in outcome measures when comparing the antibacterial drug to placebo.

99. A lengthy review of serious and sometimes permanent adverse events, including permanent peripheral neuropathy, associated with FLQ use followed the discussion of questionable efficacy for the three indications in question. The FDA cited specifically adverse event reporting from patients highlighting a "constellation of symptoms" referred to as "Fluoroquinolone-Associated Disability" (FQAD). Individuals with FQAD were defined by the FDA as patients who were prescribed an oral fluoroquinolone to treat urinary tract infections, bronchitis or sinusitis, and who experienced disabling adverse events, lasting 30 days or longer, in two of the following body systems: neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, cardiovascular.

100. After hearing testimony from industry representatives, as well as dozens of individuals who described a wide range of harmful effects on their health and cognitive ability from fluoroquinolone use, the panel voted overwhelmingly that the benefits and risks for systemic fluoroquinolone drugs do not support the current labeled indications for the treatment of ABS (unanimous), ABECB-COPD (18-2, with one abstention), or uncomplicated urinary tract infection (20-1).

101. Both the J&J and Bayer Defendants have publicly acknowledged that FLQs can cause neuropathy. At the FDA's joint advisory committee meeting in November 2015, Dr. Susan Nicholson, Vice-President of safety, surveillance, and risk management for the Johnson & Johnson Family of Companies, testified on behalf of Janssen Pharma and the other industry partners, including the Bayer Defendants.[15] Dr. Nicholson was asked the following question by the FDA subcommittee concerning quinolones and their causal relationship to tendon ruptures, severe arrhythmia, *and neuropathy*:

> Q: Dr. Winterstein [FDA]: So for the tendon piece, I think there is a fairly
> good body of literature now that looks at collagen tissue. And to me, that seems to be also a plausible mechanism for neuropathy. So I guess my question is, number one, when does it have to be a unified mechanism or what exactly did that refer to? And then number two, *does the sponsor disagree*, number one, that quinolones cause tendon ruptures, that quinolones cause severe arrhythmia, and then number three, *that quinolones cause neuropathy*? . . . So I'm just trying to get my arms around what the issue is here. *But it seems like we agree that there is a causal association with these three outcomes that we are discussing. Yes*?
>
> A: Dr. Nicholson: *Yes. We do agree*.

102. In *Conte v. Wyeth, Inc*., 168 Cal. App. 4th 89, 94 (Cal. Ct. App. 2008), the court held that under California law "the common law duty to use due care owed by a name-brand prescription drug manufacturer when providing product warnings extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a

[15] As noted at the meeting by Melissa Tokosh, global regulatory leader with Janssen Research and Development, "Our participation [at this hearing] represents a collaborative effort between both branded and generic companies, with Bayer and Janssen leading the preparation of the background documents and presentation based on data from our products."

medication, even if the prescription is filled with the generic version of the prescribed drug."

103. In *Wyeth, Inc. v. Weeks*, 159 So.3d 649, 676 (Ala. 2014), the court held "[u]nder Alabama Law, a brand-name-drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacturer of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company." The Alabama Legislature subsequently passed legislation that was signed into law prohibiting claims by generic consumers against brand-name manufacturers, effectively overruling the Alabama Supreme Court's ruling in *Weeks*. The law took effect November 1, 2015, thus barring any such cause of action filed after that date.

104. In *Kellogg v. Wyeth*, 762 F.Supp.2d 694, 709 (D.Vt. 2010), the court held "under Vermont's negligence law it is reasonably foreseeable that a physician will rely upon a brand name manufacturer's representations—or the absence of representations—about the risk of side effects of its drug, when deciding to prescribe the drug for a patient, regardless of whether the pharmacist fills the prescription with a generic form of the drug. Vermont allows a negligence action against one who owes a duty of care and fails to conform to the standard of conduct required."

105. In *Dolin v. Smithkline Beecham Corp*., 62 F.Supp.3d 705, 720-21 (N.D. Ill. 2014), the court held that under Illinois common law, a brand-name manufacturer owes a duty of care to the generic consumer.

106. Thus, under the laws of California, Alabama (before November 1, 2015), Vermont, and Illinois, the Bayer Defendants' and J&J Defendants' duty of care in disseminating product information extends to those patients, such as Plaintiffs, who have been injured by generic ingestion of any FLQ (e.g., ciprofloxacin, moxifloxacin, and/or levofloxacin) as a result of prescriptions written in reliance on Defendants' product information for such drugs. Defendants knew or should have known that prescribing physicians would rely upon the warnings or product labeling disseminated by the Defendants for Cipro, Avelox and/or Levaquin in prescribing brand-name or generic ciprofloxacin, moxifloxacin and/or levofloxacin for patients, such as Plaintiffs.

APPLICATION OF THE STATUTE OF LIMITATIONS

107. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

108. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and their treating physicians the true risks associated with Defendants' FLQ drugs, including the actual incidence of FLQ-induced peripheral neuropathy, the serious, progressive and disabling nature of FLQ-induced peripheral neuropathy, the rapid onset of FLQ-induced peripheral neuropathy, and the irreversibility of FLQ-induced peripheral neuropathy.

109. The time, place and substance of the Defendants' alleged fraud is set forth as follows. Between 1995 and 2002, FLQs became the most commonly prescribed class

of antibiotics to adults in the United States.[16] The explosive increase in FLQ prescriptions was a direct result of Defendants' deliberate decision to reframe FLQs from a "big gun" antibiotic that should be reserved for serious infections to a "first choice" antibacterial that is appropriate for a wide range of mild infections.

110. As the J&J Defendants explained in their 2003 Levaquin brand plan: "In late 2000 through mid 2001, after extensive market research and segmentation analysis, the LEVAQUIN brand team made the decision to reposition LEVAQUIN from a 'big gun' anti-infective used in serious/recalcitrant infections, to a product that is effective in fighting more common infections where growth potential was the greatest, such as bronchitis and sinusitis. A new message, based on the research and segmentation analysis was implemented beginning in August of 2001." In 2004 the J&J Defendants were still strategizing on ways to prevent Levaquin "from being pigeon-holed into the more severely ill patient." The Bayer Defendants likewise marketed Avelox and Cirpo for routine infections even though they knew that FLQs should be reserved for more serious conditions.

111. One key obstacle to Defendants' re-branding scheme was their awareness of the nature and extent of peripheral neuropathy that could result from taking FLQs. Defendants had long been on notice that FLQs were associated with serious nerve injuries. For example, by the mid-1990s the J&J Defendants knew from their own

[16] *See* Linder, JA. et al. Fluoroquinolone prescribing in the United States: 1995 to 2002. *Am J Med.* 2005 Mar;118(3):259-68 ("Fluoroquinolone prescribing increased threefold in outpatient clinics and emergency departments in the United States from 1995 to 2002. Fluoroquinolones became the most commonly prescribed class of antibiotics to adults in 2002.").

postmarketing experience that the most frequently reported adverse events concerned the central nervous system ("CNS"). The most common CNS adverse events were "dizziness, paraesthesia and headache." Paraesthesia (or paresthesia) is a medical term that refers to a burning or prickling sensation that is usually felt in the hands, arms, legs, or feet. Paresthesia is considered a hallmark of peripheral neuropathy but is believed to be more commonly reported in clinical trials and adverse event reports due to the lack of an immediate confirmation of the diagnosis of neuropathy. Indeed, since 2004 Defendants have admitted that FLQ-associated peripheral neuropathy results in "paresthesias, hypoesthesias, dysesthesias and weakness." Thus, reports of paresthesia, hypoesthesia, dysesthesia and weakness are consistent with a person who is suffering from peripheral neuropathy, even though that person may not yet have been formally diagnosed.

112. For more than a decade, Defendants have known that paresthesia and other symptoms associated with peripheral neuropathy were among the most common side effects of FLQs.

113. In the fall of 2003, [redacted] and others on the Janssen pharmacovigilance team were engaged in evaluating the "neuropathy question". Their evaluation included a review of neuropathy adverse events. Notably, a frequency tabulation of adverse events for Levaquin through May 31, 2003 demonstrated that there were numerous reports of symptoms of peripheral neuropathy, including paraesthesia, hypoesthesia, and weakness. The total number of such reports during this period was 421. During the same period there were 246 reports of headaches, 377 reports of insomnia,

421 reports of dizziness, and 489 reports of nausea. Thus, the reports of neuropathy-associated symptoms exceeded the number of reports of headaches and insomnia and were comparable to the frequency of dizziness and nausea.

114. A review of adverse events performed by the J&J Defendants in early 2006 shows very similar results. In the tabulation of adverse event frequency, there were at least 640 reports of peripheral neuropathy or symptoms indicative of peripheral neuropathy. Compare this with 351 cases of headache, 529 cases of diarrhea, 577 cases of insomnia, 633 cases of dizziness and 716 cases of nausea.

115. The Bayer Defendants were also well aware that the frequency of peripheral neuropathy symptoms was at least on par with incidence of more minor side effects. For example, during the period from May 22, 2000 to May 31, 2002, there were 145 reports of neuropathy or neuropathy symptoms, as compared to 76 reports of headaches, 107 reports of vomiting, and 260 reports of dizziness. In addition, during the period from May 31, 2007 to May 31, 2008, the Bayer Defendants received 266 reports of neuropathy or symptoms associated with neuropathy in Avelox users. During this same time frame they received 73 reports of headaches, 151 reports of vomiting, and 265 reports of dizziness. During the period from June 1, 2010 to May 31, 2012, there were 4,295 reports of neuropathy or neuropathy symptoms, as compared to 1,358 reports of headaches, 2,344 reports of vomiting, 4,136 reports of nausea, and 4,227 reports of dizziness. Thus, for the majority of time that Avelox was sold and marketed by the Bayer Defendants, neuropathy and symptoms indicative of neuropathy remained among the frequently reported adverse effects among Avelox users.

116. Given their close association with peripheral neuropathy, the frequent occurrence of paraesthesia, hypoesthesia and other neuropathy symptoms among FLQ users posed a significant hurdle to Defendants' stated goal of expanding the use of FLQs for mild infections. If practitioners were adequately warned about the risk of serious peripheral neuropathy, they would be much more hesitant to prescribe FLQs for the type of routine infections that Defendants were targeting through their marketing strategies. So Defendants elected to conceal the true nature of the risk.

117. In order to continue to trumpet the allegedly "excellent" safety profile of FLQs, Defendants had little choice but to omit any discussion of the significant risk of paraesthesia, hypoesthesia, dysesthesia and weakness (with their implication for the risk of peripheral neuropathy), and instead focus on what would be perceived as more mild and acceptable side effects, such as headaches or nausea.

118. Beginning in at the late 1990s, Defendants aggressively marketed FLQs while at the same time concealing, through misrepresentations or omissions, the risk of peripheral neuropathy. They did this by focusing on the incidence of relatively benign side effects, such as headaches or dizziness, while concealing the equally common but far more serious symptoms of peripheral neuropathy.

119. In a 2000 press release, the Bayer Defendants announced that Avelox exceeded two million patient uses worldwide since its international product launch in 1999. The press release went on to proclaim that spontaneous adverse event reporting from 1.58 million patient uses was low, with the most frequent reported events being nausea, vomiting and dizziness. The press release quotes Dr. Posner, Bayer

Corporation's Head of Global Regulatory Affairs, as saying: "Postmarketing surveillance data are used by the FDA to assess the continued safety of approved drugs. Our study offered the opportunity to affirm that Avelox is safe and generally well-tolerated."

120. Thus, in their nationwide marketing campaigns to physicians touting Avelox's excellent safety profile, the Bayer Defendants concealed any mention of neuropathy symptoms despite disclosing more mild and less frequent side effects. The Bayer Defendants fully intended for physicians to rely on their assurances of safety and concealment of the actual safety profile when choosing to prescribe Avelox for routine infections.

121. The J&J Defendants likewise instituted a marketing campaign that was designed to promote Levaquin's "excellent" safety profile by disclosing the occurrence of only mild symptoms while concealing the presence of more serious and more frequent symptoms of peripheral neuropathy. In doing so, the J&J Defendants misled physicians regarding the true risks of Levaquin.

122. A 2001 advertisement promoting Levaquin as a first choice for bronchitis and sinusitis points out Levaquin's "unmatched safety profile" and mentions the following adverse events: nausea, diarrhea, insomnia, dizziness and "other side effects." Similarly, in a 2002 Levaquin advertisement promoting Levaquin as the first choice for acute bacterial exacerbation of chronic bronchitis, Defendants point out Levaquin's proven safety profile and highlight the following adverse events: nausea, diarrhea, insomnia and dizziness.

123. Defendants' sales forces promoted FLQs to physicians through "details" or sales calls to physicians' offices. On these sales calls, sales representatives – often using a sales aid and/or sales script developed by Defendants' marketing teams – "detail" the physician on various uses of Defendants' products. For example, one 2004 Levaquin detail script began by explaining that the purpose of the call was to discuss "the use of LEVAQUIN in the treatment of acute maxillary sinusitis." The script continued by pointing out the safety profile of Levaquin, noting a "very low incidence of both GI and CNS adverse events, including a much lower rate of diarrhea compared with Augmentin." This statement was false and misleading and constituted blatant concealment of the product's actual risk profile because the J&J Defendants were aware that CNS adverse events occurred frequently among FLQ patients. Additionally, the comparison with Augmentin was especially misleading because it suggested that the safety of FLQs was superior to Augmentin, even though Augmentin carries much less severe side effects then FLQs. The J&J Defendants concealed the superiority of Augmentin from physicians.

124. In a 2004 sales aid, J&J's sales representatives were being trained to effectively convince physicians and other medical personnel to prescribe Levaquin over other FLQs by emphasizing the drug's safety profile. In one script, these sales representatives were given these "catchy phrases" to use: "Levaquin is 'tried and true' in 300 million patients over the past 10 years. Bottomline, doctor, you know what you're getting when you prescribe Levaquin. No surprises! If safety issues were going to crop up, you'd know it by now, unlike the newer quinolones, which are unproven in a limited

patient population." Another sales technique was to recklessly compare Levaquin to candy: "M&M bags of candy – Doctor, when you think of Levaquin, think of M&Ms. Levaquin is mild on the belly and mean on the bugs."

125. In a 2007 sales aid, the J&J Defendants pointed to Levaquin's safety profile and noted that the most common adverse drug reactions in US clinical trials were nausea, headache, diarrhea, insomnia, constipation and dizziness while concealing the most serious side effects they knew to exist.

126. In a November 2007 advertisement promoting Levaquin as the first choice for acute maxillary sinusitis, the J&J Defendants trumped Levaquin's "excellent safety" profile, citing the following adverse events: nausea, diarrhea, insomnia, and dizziness. Defendants again concealed Levaquin's true risk profile.

127. The J&J Defendants made similar representations in their promotional "patient brochures" aimed at patients and physicians. For example, in one "patient brochure" from 2010 the "intended audience" was "Healthcare Professionals and Patients." The "objective" of the brochure was for the brochure to be "left behind" in the "HCP [Healthcare Professional's] waiting and exam room that *capture the attention* of bacterial RTI patients and highlight the coupon." This brochure, whose theme was "A Step Ahead," states that "LEVAQUIN has been shown to be a safe and effective way to treat certain bacterial infections such as ABS [acute bacterial sinusitis] ABECD [acute bacterial exacerbation of chronic bronchitis]." This brochure further represents that "The most common side effects include dizziness, headache, constipation, nausea, and diarrhea."

128. Plaintiffs' treating physicians would have received some form of these marketing materials, and with them the repeated misrepresentations and concealment regarding FLQs' safety profile and the concealment of the risk of irreversible peripheral neuropathy and associated symptoms.

129. Despite the claims in their marketing materials, Defendants were aware that paraesthesia and other symptoms indicative of peripheral neuropathy had occurred frequently in FLQ patients. Defendants' marketing materials deliberately omitted any mention of neuropathy-type symptoms in their laundry list of side effects, even though the neuropathy symptoms occurred with similar, if not greater, frequency than the headaches, constipation, nausea, diarrhea, insomnia and dizziness they repeatedly mentioned.

130. Failing to disclose the high incidence of neuropathy and neuropathy-associated symptoms was not the only way in which Defendants concealed the true risk of FLQ-induced peripheral neuropathy. Defendants also misrepresented the extent of the injury. They did this in at least three ways. First, they concealed the true risk of irreversible peripheral neuropathy. Second, they concealed the fact that the irreversible peripheral neuropathy caused by FLQs is often the result of a rapid onset of symptoms – in other words, a patient could suffer permanent nerve injuries after taking as few as one or two FLQ pills. Third, Defendants misrepresented the severity of the injury and failed to disclose that it can be serious and disabling.

131. Defendants knew at least by the mid-1990s that FLQs were capable of inducing prolonged, irreversible peripheral neuropathy. This knowledge came from the

numerous adverse event reports Defendants received during this period. Defendants concealed these reports from the medical community. Just a few examples of these reports are included below:

- In a 1994 report from Japan, a patient was started on levofloxacin on July 7 at noon. That evening the patient developed numbness. Levofloxacin was discontinued on July 12. The patient had a nerve biopsy suggestive of axonal neuropathy. In an addendum about this patient's progress several months later (December 6, 2004), it was noted of the patient that "Walking by herself was impossible (she was confined to a wheelchair most of the day)." In performing a causality assessment, the J&J Defendants concluded that "Paraesthesia may occur under quinolones." They also agreed with the reporting physician that toxic neuropathy is also suspected.
- An adverse event report from May 1997 documented a patient/physician who took Levaquin and developed peripheral neuropathy. The reporter determined the patient's peripheral neuropathy was "Very Likely/Certain" caused by Levaquin. After conducting a causality assessment, the J&J Defendants concluded it was "probable" the patient's peripheral neuropathy was caused by Levaquin. J&J received updated reports on this patient on several occasions in 1998 and 1999 and retained its causality determination of "probable" while also indicating the patient's peripheral neuropathy never resolved.

- A 1998 report documented that a Levaquin patient had developed neuropathy that left the patient "unable to work and housebound." The neuropathy had not resolved even months after the patient discontinued the Levaquin.
- A report from August 2000 detailed a patient that started suffering from polyneuropathy with burning sensations in the feet and legs on the second day of Levaquin therapy. The patient did not recover.
- The J&J Defendants received another report in 2000 of a patient who had taken four days of Levaquin and suffered from demyelinating polyneuropathy that had not resolved at the time of the report, approximately 3 months later.
- The J&J Defendants received multiple reports in 2001 that confirmed the rapid and long-term danger posed by Levaquin. For example, a report received in May of 2001 detailed a patient that was prescribed Levaquin to treat sinusitis and that within 6-hours of the first dose began experiencing paraesthesia of the hands and feet, forcing him to discontinue treatment after three days. Several months later the patient was again prescribed Levaquin and he suffered a second adverse event. The patient had not recovered as of the last report. In September 2001 another report was received by the J&J Defendants describing a patient who was given Levaquin and by the tenth day of treatment developed polyneuropathy. The reporter assessed the causal relationship between this event and Levaquin as "highly probable".
- The Bayer Defendants received an adverse event report in 2000 involving a patient who exhibited symptoms of "numbness of hands, feet and fingers

(hypesthesia)"and "paresthesia" following use of Bayer's FLQ drug and who had not fully recovered from these symptoms a year later. Additional reports were received by the Bayer Defendants in 2002 of patients who experienced symptoms of "pins and needles in hands (paresthesia)" who had "not recovered" and whose symptoms were "ongoing" at time of last reporting.

- A 2003 report noted that a patient's disabling neuropathy had still not resolved almost two years after the Levaquin was discontinued.
- A 2005 report described a patient who was given Avelox and on the fourth day of treatment developed "pain in both legs," which was reported as "neuropathy." A month later, "pain in one leg persisted, and a drop foot developed."

132. Many of the foregoing reports highlight the rapid onset of peripheral neuropathy. In addition, numerous other early adverse event reports reviewed by Defendants provided ample indication of the rapid onset of permanent nerve damage – information not provided to the medical community. Examples include:

- An October 2000 report described a patient who developed paresthesia in his arms and legs within 24 hours of taking Avelox.
- A 2001 report noted a patient who developed neuropathy within a day of taking Avelox and the neuropathy had not resolved at the time of the report.
- A July 2002 report of a 48 year old female was treated with Levaquin and within three days she experienced neuropathy.

- A July 2004 report described a 23-year old female patient who began treatment with Levaquin at noon and by that evening she was experiencing numbness. A subsequent nerve biopsy indicated axonal neuropathy. The adverse event report indicated that the patient suffered from numbness, pain, and twinges and muscle weakness in her extremities.

133. The potential for rapid onset of neuropathy symptoms was also apparent in the Levaquin clinical trials. In a Phase I study conducted in 1999, one of the study subjects developed paresthesia after taking just a single dose, and this adverse event was considered to be "probably related" to study medication by the study investigator.

134. Defendants were also aware of, and concealed, the fact that, while many patients experience a rapid onset of symptoms, other patients suffered injuries after a delay in onset even though they only took the FLQ for a week or two. One such example is a patient that reported taking Levaquin for 14 days at which point he discontinued therapy due to tendinitis. After discontinuation of the drug, he later experienced peripheral neuropathy presenting with numbness in his hands and feet, and his symptoms were persistent at the time of the report. Id.

135. Defendants also concealed the severity of the permanent peripheral neuropathy caused by FLQs. In numerous adverse event reports, Defendants learned of the serious and disabling nature of the irreversible peripheral neuropathy that can result from FLQ use. In addition to those previously mentioned, a 2002 report described a 46-year old man who developed symptoms after starting Levaquin treatment and eighteen months after stopping treatment still needed a cane to ambulate.

136. In 2003 the J&J Defendants conducted an in-depth review of post-marketing adverse event reports to determine whether a warning regarding the risk of peripheral neuropathy was merited. This review identified "numerous cases [of peripheral neuropathy] without apparent alternative explanations which could represent causality associated with the use of levofloxacin." The review noted the potential for rapid onset and concluded that the reports were "consistent with causal association for both levofloxacin and ofloxacin."

137. In connection with a 2004 review of peripheral neuropathy adverse event reports from the previous twelve-month period, the J&J Defendants identified at least five separate reports. Upon reviewing these reports, the J&J Defendants learned that none of the five reports indicated the neuropathy had resolved. Thus, in 100% of the reported cases, the J&J Defendants did not have any reason to believe that the neuropathy was reversible. Similarly, the review of these five cases revealed that the date of symptom onset ranged from 1 to 5 days after starting Levaquin, which highlighted yet again the problem of rapid onset. Yet the J&J Defendants revealed none of this to the medical community or prospective patients.

138. In 2006 the J&J Defendants again confirmed they were fully aware of the true risk of their product. In a report by [redacted] and [redacted] of the Benefit Risk Management team, a detailed review of 263 reported cases of peripheral neuropathy led to the conclusion that the onset of symptoms "appeared to be rapid in some cases" and that "there was evidence of longer-term sequelae."

139. The aforementioned internal reports and analyses underscore the extent to which Defendants were on notice that their FLQs could cause rapid onset of a permanent and severe peripheral neuropathy. But the disclosure of a permanent, disabling nerve injury that could occur after taking one or two doses of their FLQs would undercut and disrupt Defendants' marketing strategy. So instead of disclosing the risk of such an injury, Defendants chose to conceal it.

140. In order to appreciate the significance of Defendants' concealment, including both omissions and misrepresentations, regarding the extent and nature of the risk of FLQ-induced irreversible peripheral neuropathy, it is important to understand the prevailing wisdom among medical professionals regarding the nature of drug-induced peripheral neuropathy. Physicians are generally taught that the various forms of drug-induced peripheral neuropathy have two traits in common. First, they develop only after prolonged use of the offending drug, in the range of several weeks to months.[17] Second, they are transient in nature, and resolve after the drug is discontinued.[18] While there are instances where a drug-induced neuropathy may fail to resolve and become a permanent

[17] *See*, *e.g.*, Ropper A. et al., Principles of Neurology – Tenth Edition, p. 1336, McGraw-Hill Education (2014) (most drug-induced neuropathies occur "after large cumulative doses of the drug have been given (e.g., in cancer chemotherapy) or after prolonged administration"); Benichou C., Adverse Drug Reactions: A Practical Guide to Diagnosis and Management, pp. 105-109, J. Wiley & Sons (1994) ("Most drug-induced polyneuropathies are subacute having an onset of a few weeks or months.").

[18] *See* Vilholm O.J. et al. Drug-Induced Peripheral Neuropathy. *Basic & Clinical Pharmacology & Toxicology* 2014 Aug; 115(2):185-192 ("Drug-induced peripheral neuropathy can begin weeks to months after initiation of treatment with a particular drug and reach a peak at, or after, the end of treatment. In most cases, the pain and paraesthesia completely resolve after cessation of treatment.").

condition, doctors are typically led to believe that this would only occur when the patient had been taking the drug for an extended period of time.

141. Thus, Defendants' failure to disclose the unique characteristics of FLQ-induced peripheral neuropathy—including rapid onset, irreversibility, and severity—meant that Plaintiffs' treating physicians, when tasked with determining the cause of Plaintiffs' peripheral neuropathy, would not "rule in" FLQs as a potential cause and thus FLQ use was excluded from their differential diagnosis. After all, these physicians would have assumed that the rapid onset of Plaintiffs' symptoms, combined with their persistence even after discontinuation of FLQ treatment, eliminated FLQs as a possible cause. Simply put, Plaintiffs' treating physicians believed that drug-induced irreversible peripheral neuropathy does not occur in these situations, and prior to August 2013, they would have had no reason to believe any differently for FLQ-induced peripheral neuropathy. As noted herein, however, the current label for Levaquin remains misleading regarding the risk of developing irreversible peripheral neuropathy.

142. Defendants fraudulently concealed from physicians, patients, and the medical community that the development of peripheral neuropathy could be permanent. Defendants failed to disclose this important safety risk to patients or the medical community.

143. It was not until September 2004 that Defendants provided any kind of warning to Plaintiffs or their physicians regarding the risk of peripheral neuropathy. It was at this point in time that Defendants warned that "rare" cases of "polyneuropathy . . . resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in

patients receiving quinolones." This warning failed to disclose the true risk of irreversible peripheral neuropathy, the possibility of rapid onset, or the serious and disabling nature of the injury. By underscoring the "rare" incidence of neuropathy among FLQ users, Defendants reinforced the misleading statements in their marketing materials that the most frequent symptoms were minor reactions such as headaches and diarrhea.

144. Thereafter, from September 2004 through August 2013 for Levaquin and Cipro and August 2012 through August 2013 for Avelox, Defendants, through their product labeling, continued to mislead physicians, patients, and the medical community by representing that patients experiencing symptoms of peripheral neuropathy should discontinue treatment "in order to prevent the development of an irreversible condition." By including this language, Defendants misled patients and their physicians into believing that permanent peripheral neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms. This was false. Defendants knew that cases of peripheral neuropathy associated with FLQ use could be permanent, regardless of when the patient stopped taking the drug.

145. This is evidenced by Defendants' own internal documents. For instance, in August 2004 the J&J Defendants updated their Company Core Data Sheet ("CCDS")[19] to include the risk of developing "irreversible" peripheral neuropathy. Specifically, the J&J Defendants updated their CCDS to provide as follows:

[19] According to J&J's internal documents, "[i]nformation in [the] CDS is 'in principle' supposed to be core medical information to be implemented in every local labeling." Thus, there should not be a discrepancy between the CCDS and Defendants' drug labels.

> Very rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysethesias, and weakness have been reported in patients receiving quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences any of the above symptoms. *Peripheral neuropathy associated with quinolone use may be an irreversible condition* (emphasis added).

146. At the same time, the J&J Defendants concealed the irreversible nature of this condition from the medical community in the United States by representing in their FLQ labeling that patients experiencing symptoms of neuropathy should discontinue treatment "in order to *prevent* the development of an irreversible condition." Nothing else was said about the risk of irreversible peripheral neuropathy.

147. The J&J Defendants were aware of the inconsistency in risk conveyed in their internal CCDS (not for public dissemination) and the US label (for public dissemination). Indeed, by March 2005, just a few months after the US label change regarding peripheral neuropathy, the J&J Defendants held a meeting to discuss "apparent difference between CCDS and USPI [United States Product Insert] re last two sentences of CCDS" concerning the irreversibility of the condition. However, upon information and belief, the medical community was never advised by the J&J Defendants that the risk conveyed in the USPI was not scientifically justified based on their own internal "core medical information" regarding the drug's risk for developing irreversible peripheral neuropathy. It was not until almost a decade later—after the expiration of their patent on Levaquin—that the true irreversible nature of the condition was included in the USPI. Even still, the FLQ labeling in the USPI remains deficient and confusing.

148. Defendants had a duty to disclose all facts about the risks associated with use of the medication. However, Defendants failed to disclose in their FLQ labels that the onset of peripheral neuropathy is often rapid, that discontinuation of the drug will not ensure that the peripheral neuropathy is reversible, or that neuropathy symptoms were among the most common side effects (and certainly were not rare).

149. Further, upon information and belief, Defendants intentionally misrepresented the number of reported cases of peripheral neuropathies by improperly excluding certain forms of peripheral neuropathy from the total number of cases counted towards the condition. In this way they concealed the true risk profile of their product. This allowed Defendants to falsely represent to the medical community and patients in the labeling that reported cases of peripheral neuropathy were "rare," thereby vastly minimizing the risk.

150. For example, in the fall of 2004 the J&J Defendants reported that they received only 5 adverse drug reaction ("ADR") reports of peripheral neuropathy during the period from October 2003 to September 2004. However, the J&J Defendants were in fact aware of many other reports of peripheral neuropathy during this same time period that they excluded from their count of peripheral neuropathy cases. These include:

- AER NSADSS2002023094: a report of "peripheral neuropathy"
- AER NSADSS2003014295: a report of "polyneuropathy" (Defendants use the terms "polyneuropathy" and "peripheral neuropathy" interchangeably)
- AER NSADSS2003024330: a report of "neuropathy peripheral"

- AER NSADSS2003017842: a report of "neuropathy" in which the symptoms include tingling in the limbs and numbness in the fingers and toes
- AER NSADSS2002039226: a report of "neuropathy" in which the symptoms included tingling in the foot and legs
- AER NSADSS2002043399: a report of "neuropathy" in which there were symptoms reported in the arms and legs
- AER JP-JNJFOC-20030901883: a report of "neuropathy" in which the patient reported tingling and numbness in her feet and fingers

151. In a summary of adverse event reports generated in 2002, the J&J Defendants repeatedly altered the original reporting terms so that numerous reports of peripheral neuropathy were ignored. Examples include the following adverse event reports:

- AER NSADSS2001008976: a report of "burning neuropathy" was changed to "paraesthesia"
- AER NSADSS2001016934: a report of "polyneuropathy" was changed to "neuropathy"
- AER NSADSS2001021557: a report of "peripheral neuropathy" was changed to "paraesthesia"
- AER PRIUSA1999003597: a report of "polyneuropathy" was changed to "neuropathy"

- AER PRIUSA2000001269: a report of "axonal demyelinating polyneuropathy" was changed to "neuropathy"
- AER PRIUSA2000001431: a report of "polyneuropathy" was changed to "neuropathy"
- AER PRIUSA2000002025: a report of "polyneuropathy" was changed to "neuropathy"

152. Another way in which the J&J Defendants concealed the incidence of peripheral neuropathy was by manipulating the terms that were used to search for reports of peripheral neuropathy. The J&J Defendants were aware that by choosing only a narrow group of search terms, they could ensure that the number of peripheral neuropathy adverse events they must report would be reduced by almost 80%.

153. The Bayer Defendants have likewise adopted procedures to conceal the extent and nature of the risk of irreversible neuropathy. For example, when reporting on the incidence of Avelox-induced peripheral neuropathy in 2009, the Bayer Defendants intentionally excluded all cases that exhibited a rapid onset of symptoms. In defense of this decision, the Bayer Defendants cited a leading textbook which stated that drug-induced peripheral neuropathies have an onset "of a few weeks or months." The problem, of course, was that the Bayer Defendants knew long before 2009 that, in the case of FLQ-induced neuropathy, the time to symptom onset is very rapid, including after a single dose. Yet the Bayer Defendants never disclosed this knowledge to the medical community. Thus, by excluding cases of rapid onset, the Bayer Defendants knew they would avoid having to report the majority of Avelox- and Cipro-induced peripheral

neuropathies. As they wrote in their 2009 report: "In the majority of reports the treatment duration is well shorter than 8 days, in many reports the onset is within hours after a single dose. . . . Thus, applying the definitions as stated in the method-section, no cases of (poly-)neuropathy could be identified, and the association of the reported clinical symptoms with moxifloxacin was either excluded or unlikely in the final evaluation." The low incidence of FLQ-associated irreversible peripheral neuropathy therefore became a self-fulfilling prophecy, since Defendants' criteria for such an association excluded the very characteristic (rapid onset) that is a hallmark of the association.

154. Defendants, including the Bayer Defendants specifically, have publicly recognized that FLQs should not be used as a first-line treatment for uncomplicated or minor infections, such as acute maxillary sinusitis, acute exacerbation of chronic bronchitis, and uncomplicated urinary tract infections. [redacted], senior director, global clinical development at Bayer Healthcare, recently testified before the FDA that "Quinolones are definitely an alternative, but no one is recommending them as a first line [treatment] for the uncomplicated cases."[20] Contrary to this representation, Defendants marketed and promoted FLQs for more than a decade to physicians, hospitals, and the medical community as a first-line treatment for uncomplicated infections, including sinusitis, bronchitis, and urinary tract infections. All the while, Defendants concealed from the medical community that opinion leaders, including its own personnel, acknowledged that the product was inappropriate for such use.

[20] Testimony of [redacted], senior director, global clinical development at Bayer Healthcare, at the FDA Subcommittee Advisory Hearing, Nov. 5, 2015.

155. Defendants were obligated under federal regulations to revise the labeling as soon as there was reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved. 21 C.F.R. 201.57(e). Despite the information known to Defendants discussed above, Defendants deliberately failed to update their FLQ labels to reflect the rapid onset of symptoms or the risk of developing *permanent* peripheral neuropathy or the severity of nerve damage or the higher incidence of neuropathy symptoms. Defendants knew, prior to Plaintiffs' use of the FLQ drugs, that central nervous system-related effects were one of the most common adverse effects of quinolones and that the onset of events like peripheral neuropathy could be rapid and irreversible. Despite this information, Defendants deliberately failed to update their FLQ labels, marketing materials, or educational and promotional documents and statements to reflect this important safety information or to modify their marketing materials and mantras.

156. In failing to update their labels and marketing materials, Defendants intended that that the misinformation contained in the label would be relied upon by Plaintiffs and their prescribing physicians, which it was. As a direct result of Plaintiffs and their prescribing physician's reliance on the false information contained within the FLQ labels, Plaintiffs were prescribed and took Defendants' FLQs and developed permanent peripheral neuropathy.

157. The nature of Plaintiffs' injuries and the relationship of such injuries to FLQs were inherently undiscoverable prior to the full dissemination of the FDA disclosure of risk information that began in August 2013.

158. Accordingly, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through reasonable care and diligence should have known, of their claims against Defendants, and in any event such tolling should continue until at least the date of FDA's disclosure of risk information in August 2013.

159. Plaintiffs did not discover, and through the exercise of reasonable care and due diligence should not and could not have discovered, their illnesses and injuries or their relationship to the FLQ drugs until after August 2013. Plaintiffs' suit is filed well within the applicable statute of limitations period under appropriate application of their state's "discovery rule."

160. In the alternative, the facts of Plaintiffs' claims made it impossible for them to discover the true nature of their injuries and/or causes of action within the applicable limitations period. In particular, Defendants' misrepresentations and omissions that constituted active concealment regarding the true nature of the risks associated with their FLQ drugs prevented Plaintiffs from discovering the wrongful acts on which their causes of action are based. Prior to August 15, 2013, Plaintiffs' treating physicians denied, ignored or were unaware of any possibility that Plaintiffs' injuries were causally associated with FLQs. This was the result of Defendants' omissions from and misrepresentations to the medical community and to the general public. Indeed, in many instances, Plaintiffs' treating physicians stated that the permanent nature of Plaintiffs' injuries meant that they could not have been caused by FLQs, since Defendants had falsely promoted their FLQs resulting in physicians holding the mistaken belief that the

nature of injuries reported by Plaintiffs—irreversible peripheral neuropathy—could not be caused by FLQs. As a result, Plaintiffs were told their injuries were due to some other potential cause(s), or that the cause of their injuries was not knowable or "idiopathic." Thus, while Plaintiffs acted diligently to determine both the nature and the cause of their injuries, their efforts were thwarted by Defendants' fraudulent concealment. Plaintiffs filed this lawsuit within the applicable limitations period of the date they knew or through the exercise of reasonable care and due diligence should have known of their claim.

161. Unlike ordinary consumers of prescription drug products, prescription drug manufacturers are held to the standard of experts on their products. And unlike ordinary consumers, prescription drug manufacturers are obligated to keep abreast of scientific knowledge, discoveries, advances and research in the field related to their products, and are presumed to know what is imparted thereby. Conversely, ordinary consumers (like Plaintiffs) are not presumed, as are drug manufacturers, to have superior or continuing knowledge of medical and scientific evidence concerning the drugs they take, particularly with respect to drugs they have previously ingested. Plaintiffs, as ordinary consumers, had no reason to suspect that their use of Defendants' FLQs might have caused or contributed to their development of permanent peripheral neuropathy until after August 2013 at the earliest because of Defendants' fraudulent concealment of the risk as noted above. In addition, physical symptoms alone, without knowing or being able to discern the cause, is insufficient to start the statute of limitations clock running. This is certainly true for those Plaintiffs whose symptoms did not begin to develop until weeks or months after their last use of the drug. It also applies to those Plaintiffs who suffered symptoms

for months or years after being prescribed FLQs but who were misdiagnosed and only later came to be correctly diagnosed with permanent peripheral neuropathy; or who were told by their treating physician(s) that their peripheral neuropathy could not be related to their FLQ usage; or who, after consulting their physicians, were not told that FLQ usage was not the cause of their injuries.

162. Plaintiffs could not have reasonably discovered the full extent of their injuries and their relationship to the FLQ drugs until some time after August 2013. It was only then that the FDA disclosed on its website that there was a risk of developing *irreversible* peripheral neuropathy with FLQ use. Before then, the relationship was not reasonably knowable by Plaintiffs.

163. Indeed, Defendants admitted in internal communications that the warning they provided to physicians and patients prior to August 2013 did not include the risk of developing irreversible peripheral neuropathy. For example, in a July 18, 2013 email a J&J employee stated that "Levaquin is labeled for peripheral neuropathy but not for irreversible peripheral neuropathy."

164. The lack of awareness concerning the causal relationship between FLQs and irreversible peripheral neuropathy was not the result of silence or passive concealment. Defendants, through their marketing statements and labeling, made affirmative representations and engaged in deliberate omissions to the medical community and patients, both of which suggested, both expressly and impliedly, that symptoms of neuropathy were reversible, thereby excluding suspicion of any drug-induced relationship or cause and preventing subsequent discovery.

165. The mere publication of the risk information on the FDA's website in August 2013 did not provide the general public or the medical community with information sufficient to arouse suspicion of a relationship between FLQ use and permanent peripheral neuropathy. There was no widespread media coverage, and Defendants failed to provide any additional substantive disclosure to the general public about the label change or risk information, whether in the form of website communication, newspaper or television advertisements. Plaintiffs' duty to investigate does not begin to run until Plaintiffs actually have a reason to investigate. Defendants' affirmative representations in their FLQ labels prior to August 2013 foreclosed any such duty or suspicion because, according to the labeling, FLQ-induced neuropathies were reversible once the drug was discontinued. Accordingly, it was only well after August 2013 that Plaintiffs may be said to have had a reason to investigate the cause of their permanent peripheral neuropathy. In the alternative, a diligent investigation would not have uncovered FLQ use as the cause of Plaintiffs' injuries, for the reasons expressed above.

166. Even in the absence of the application of a "discovery rule," Plaintiffs have timely filed their claims from their dates of injury, which dates will vary by Plaintiff. Plaintiffs further aver that before addressing when an injury arises for statute of limitations purposes, it is necessary to first identify the actionable injury. Once the actionable injury is identified, the determination will have to be made as to when it occurred and the party asserting the limitations bar bears the burden of proving this

within a reasonable degree of medical certainty, which will be a case-by-case determination.

167. As a result of Defendants' actions, Plaintiffs and their treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

168. Therefore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality, and nature of their FLQs. Defendants were under a duty to disclose the true character, quality, and nature of their FLQs because this was non-public information over which Defendants had and continue to have exclusive control, and because Defendants knew that this information was not available to the Plaintiffs, medical providers and/or to their facilities. Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

169. Further, Plaintiffs had no knowledge that Defendants were engaged in the wrongdoing alleged herein, and because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiffs could not have reasonably discovered the wrongdoing at any time prior.

170. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent conduct, as described in the preceding paragraphs. Defendants, through their affirmative misrepresentations and omissions, actively concealed from

Plaintiffs and Plaintiffs' prescribing physicians and healthcare providers the true and significant risks associated with FLQ use.

171. As a result of Defendants' fraudulent actions, Plaintiffs and Plaintiffs' prescribing physicians and healthcare providers were unaware and could not have reasonably known or learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations. Plaintiffs have been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Defendants actively concealed from Plaintiffs and/or Plaintiffs' physicians the true risks associated with the use of their FLQ drugs. Defendants' acts and omissions included failing to disclose the truth about the safety and efficacy of their FLQ drugs to Plaintiffs' physicians and/or Plaintiffs, and concealing through misrepresentation the safety and efficacy of their FLQ products. Plaintiffs and Plaintiffs' physicians reasonably relied on Defendants to disseminate truthful and accurate safety and efficacy information about their drugs and warn of the side effects complained of herein.

172. Although some aspect of the injury may have been known to Plaintiffs and Plaintiffs' physicians, due to Defendants' intentional concealment, an essential fact to bring their cause of action was unknown. Plaintiffs, lacking the reasonable means to discover vital information, reasonably relied on the concealment of essential facts that Defendants, having actual knowledge of material facts, actively and deliberately concealed with the intent to prevent discovery thereof by others, including the Plaintiffs.

As a consequence of Defendants' conduct, Plaintiffs were without knowledge of those facts and without means to discover them within the period of the statute of limitations, thereby relying to their detriment on Defendants' conduct.

173. As such, the running of any statute of limitations has been tolled by reason of Defendants' affirmative misrepresentations and omissions.

174. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the defective nature of FLQs. Defendants, at all times relevant hereto, were under a duty to disclose the true character, quality and nature of FLQs because this was non-public information over which the Defendants had and continue to have exclusive control, and because Defendants knew this information was not available to the Plaintiffs or Plaintiffs' physicians. In addition, Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

175. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug, often as a front-line therapy for minor infections, notwithstanding the known or reasonably known risks. Plaintiffs and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations. Accordingly, Defendants are precluded by the discovery rule, the doctrine of fraudulent concealment and/or the doctrine of equitable estoppel from relying upon any statute of limitations.

176. Had Plaintiffs' physicians known of the true risk profile of Defendants' products, the physicians would not have prescribed the products to Plaintiffs. Had Plaintiffs' physicians known of the true risk profile of Defendants' products, the physicians would have transferred this information to Plaintiffs. Had Plaintiffs known of the true risk profile of Defendants' products, Plaintiffs would have declined to use those products. The physicians would have honored Plaintiffs' wishes by failing to prescribe the product.

177. Neither Plaintiffs nor their physicians were aware of the true risk profile of Defendants' products before Plaintiffs were injured. Plaintiffs learned that Defendants' products might be responsible for their injuries within the proscriptive periods prescribed by the state law governing Plaintiffs' claims.

178. For each Count hereinafter alleged and averred, the above and following Paragraphs should be considered re-alleged as if fully rewritten.

COUNT I

[Strict Liability]

179. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

180. The FLQ drugs manufactured, marketed, supplied and/or distributed by Defendants and McKesson were defective at the time of manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying such labels failed to warn of the

dangerous risks they posed, including the risk of developing irreversible peripheral neuropathy.

181. At all times alleged herein, the FLQs manufactured, marketed, supplied, and/or distributed by Defendants and McKesson were defective, and Defendants and McKesson knew that their FLQ drugs were to be used by consumers without inspection for defects. Moreover, Plaintiffs, their prescribing physicians, and their healthcare providers neither knew nor had reason to know at the time of Plaintiffs' use of the drugs of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants and McKesson failed to include the appropriate warnings.

182. At all times alleged herein, the Defendants' FLQs were prescribed to and used by Plaintiffs as intended by Defendants and McKesson and in a manner reasonably foreseeable to Defendants and McKesson.

183. The design of Defendants' FLQ drugs were defective in that the risks associated with using the drugs as a first-line therapy for infections that did not dictate the use of an FLQ outweighed any benefits of their design. Any benefits associated with the use of the FLQs in such situations were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results but without the increased risk of developing irreversible peripheral neuropathy.

184. The defect in design existed when the products left Defendants' and McKesson's possession.

185. At the time FLQs left the control of Defendants and McKesson, Defendants and McKesson knew or should have known of the risks associated with ingesting their drug.

186. As a result of the defective condition of Defendants' FLQs, Plaintiffs suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT II

[Product Liability – Failure to Warn]

187. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

188. Defendants and McKesson have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting their FLQ drugs and, through that conduct, have knowingly and intentionally placed such drugs into the stream of commerce with full knowledge that their products reach consumers such as Plaintiffs who ingested them.

189. Defendants and McKesson did in fact sell, distribute, supply, manufacture, and/or promote their FLQ drugs to Plaintiff and to their prescribing physicians. Additionally, Defendants and McKesson expected the drugs they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and they did in fact

reach – prescribing physicians and consumers, including Plaintiffs and their prescribing physicians, without any substantial change in the condition from when they were initially distributed by Defendants and McKesson.

190. At all times herein mentioned, Defendants' FLQ drugs were defective and unsafe in manufacture such that they was unreasonably dangerous to the user, and were so at the time they were distributed by Defendants and McKesson and ingested by Plaintiffs. The defective condition of such drugs was due in part to the fact that they were not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of their use.

191. This defect caused serious injuries to Plaintiffs, who used Defendants' FLQs in their intended and foreseeable manner.

192. At all times herein mentioned, Defendants and McKesson had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that their products did not cause users to suffer from unreasonable and dangerous side effects.

193. Defendants and McKesson so negligently and recklessly labeled, distributed, and promoted the aforesaid products that they were dangerous and unsafe for the use and purpose for which they were intended.

194. Defendants and McKesson negligently and recklessly failed to warn of the nature and scope of the side effects associated with their FLQ products, namely irreversible peripheral neuropathy.

195. Defendants and McKesson were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants and McKesson knew or should have known that their FLQ drugs caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy from their use, even though this side effect was known or reasonably scientifically knowable at the time of their initial marketing and distribution. Defendants and McKesson willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants and McKesson acted with a conscious disregard for the safety of Plaintiffs.

196. Plaintiffs could not have discovered any defect in the subject products through the exercise of reasonable care.

197. Defendants and McKesson, as the manufacturers and/or distributors of the FLQ products, are held to the level of knowledge of experts in the field.

198. Plaintiffs reasonably relied upon the skill, superior knowledge, and judgment of Defendants and McKesson.

199. Had Defendants and McKesson properly disclosed the risks associated with their FLQ drugs, Plaintiffs would have avoided the risk of irreversible peripheral neuropathy by not using the drugs.

200. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants and McKesson alleged herein, and in such other ways to be later shown, the subject product caused Plaintiffs to sustain injuries as herein alleged.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

COUNT III

[Negligence]

201. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

202. At all times material hereto, Defendants and McKesson had a duty to exercise reasonable care to consumers, including Plaintiffs herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of the FLQ drugs.

203. Defendants and McKesson breached their duty of reasonable care to Plaintiffs in that they negligently promoted, marketed, distributed, and/or labeled the drugs.

204. Plaintiffs' injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants and McKesson, including, but not limited to, one or more of the following particulars:

a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Defendants' FLQ drugs;

b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiffs herein, of the dangerous and defective characteristics of Defendants' FLQ drugs;

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for Defendants' FLQ drugs;

d) In promoting Defendants' FLQ drugs in an overly aggressive, deceitful, and fraudulent manner, including as a first-line therapy to treat infections for which they were not required despite evidence as to the drug's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;

e) In representing that Defendants' FLQ drugs were safe for their intended use when, in fact, the products were unsafe for their intended use;

f) In failing to perform appropriate pre-market testing of Defendants' FLQ drugs;

g) In failing to perform appropriate post-market surveillance of Defendants' FLQ drugs;

h) In failing to adequately and properly test Defendants' FLQ drugs before and after placing them on the market;

i) In failing to conduct sufficient testing on Defendants' FLQ drugs which, if properly performed, would have shown that it had the serious side effect of causing irreversible peripheral neuropathy;

j) In failing to adequately warn Plaintiffs and their healthcare providers that the use of Defendants' FLQ drugs carried a risk of developing irreversible peripheral neuropathy. In fact, prior to August 2013, Defendants were aware that their FLQ labels did not warn about irreversible peripheral neuropathy. And the J&J Defendants were also specifically aware that the risk information contained in their FLQ medication guide was not effective in conveying the risks to patients regarding Levaquin. In an internal analysis conducted by the J&J Defendants in 2010, it was noted that that "there is a continuing problem that at least half of the patients read only some or none of the [medication] guide." Moreover, of those patients who did read it, there were "low scores" on adequately conveying "information regarding risks."

k) In failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of their FLQ drugs; and

l) In failing to adequately and timely inform Plaintiffs and the healthcare industry of the risk of serious personal injury, namely irreversible peripheral neuropathy, from FLQ ingestion as described herein.

205. Defendants and McKesson knew or should have known that consumers, such as Plaintiffs, would foreseeably suffer injury as a result of Defendants' and McKesson's failure to exercise reasonable and ordinary care.

206. As a direct and proximate result of Defendants' and McKesson's carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiffs have endured pain and suffering, physical impairment, suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IV

[Breach of Express Warranty]

207. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

208. Before Plaintiffs were first prescribed Defendants' FLQ drugs and during the period in which they used the drugs, Defendants expressly warranted that their FLQ drugs were safe.

209. Defendants' FLQs did not conform to these express representations because their drugs were not safe and had an increased risk of serious side effects, including irreversible peripheral neuropathy, whether taken individually or in conjunction with other therapies.

210. As a direct and proximate result of this wrongful conduct, Plaintiffs were injured as described above.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT V

[Breach of Implied Warranty]

211. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

212. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold FLQ drugs (including Cipro, Avelox and Levaquin), and before such drugs were prescribed to Plaintiffs, Defendants impliedly warranted to Plaintiffs that these

drugs were of merchantable quality and safe and fit for the use for which they were intended.

213. Plaintiffs, individually and through their prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

214. Plaintiffs were prescribed, purchased, and used the subject products for their intended purpose.

215. Due to Defendants' wrongful conduct as alleged herein, Plaintiffs could not have known about the nature of the risks and side effects associated with the subject products until after they used them.

216. Contrary to the implied warranty for the subject products, Defendants' FLQs are not of merchantable quality, and they were neither safe nor fit for their intended uses and purposes, as alleged herein.

217. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiffs suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiffs have endured pain and suffering, suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VI

[Fraud]

218. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

219. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell their FLQ drugs, owed a duty to provide accurate and complete information regarding these drugs.

220. Defendants' advertising, marketing and educational programs, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of FLQ drugs were safe for human use, had no unacceptable side effects, and would not interfere with daily life.

221. Defendants did not properly study nor report accurately the results of their studies in terms of risks and benefits of its FLQ drugs. For instance, Defendants failed to investigate or initiate any studies or testing following the safety signal generated by Karlman, et al. in 1988, wherein the study determined that an adverse event of peripheral paresthesia was "probably related" to ciprofloxacin treatment.

222. Defendants purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of their FLQs. For instance, the J&J Defendants hired physicians, scientists, and medical communications companies (including DesignWrite, LLC) to write inaccurate and misleading scientific articles for the purpose of creating confusion so as to pollute existing scientific and medical knowledge pertaining to the risk of developing permanent

peripheral neuropathy with FLQ use. The J&J Defendants then used and relied on these inaccurate and fraudulently prepared scientific papers to defend and justify the marketing, promotions, and labeling of its FLQ drugs. At all times, Defendants knew that what they were publishing or having published was inaccurate and that this information would mislead the members of the medical and scientific communities who were studying, or more importantly, prescribing FLQ drugs.

223. The Bayer Defendants were also actively engaged in fraudulently and intentionally polluted the scientific literature related to safety and efficacy of their FLQ drugs. The Bayer Defendants did this primarily through selected Bayer physicians and other paid medical consultants and Key Opinion Leaders ("KOLs")—namely Peter Ball, [redacted],[21] Lionel Mandell, B A. Lipsky, H. Lode, Ralf Stahlmann, and Robert Owens—who regularly touted benefits of these drugs while concealing, misstating, and downplaying the known adverse and serious health effects.[22] A sample of such statements include:

> "The most common adverse effects of the fluoroquinolones involve the gastrointestinal tract, skin and CNS, and are mainly mild and reversible." Ball, P., Mandell, L., Niki, Y., Tillotson, G. Comparative tolerability of the newer fluoroquinolone antibacterials. *Drug Saf.* 1999;21:407–421.

[21] In 2000, [redacted] was the director of international scientific relations at Bayer Corporation and co-developer of Cipro and Avelox. According to one of his online biographies: "After training in medical microbiology and infectious diseases in the United Kingdom he subsequently spent 13 years at Bayer AG in the UK, US and Germany where he was instrumental in the development of ciprofloxacin and moxifloxacin as well as other drugs in the Bayer AG portfolio." *See* [redacted]

[22] *See, e.g.*, Tillotson, G.S., Rybak, J. New milestones achieved in fluoroquinolone safety**.** *Pharmacotherapy*. 2001;21:358–360; Tillotson, G.S., Ball, P. Fluoroquinolone safety profiles—a review**.** in: *Today's Therapeutic Trends.* 1. 3rd ed. Communications Media for Education Inc; 2003:419–435.

> "Ciprofloxacin is well tolerated; the incidence of adverse events is low and serious adverse events are rare." Ball, P. Safety of the new fluoroquinolones compared with ciprofloxacin**.** *J Chemother*. 2000;12:8–11.
>
> "A review of 37 published clinical trials in more than 3,500 patients, as well as data obtained from Bayer Corporation, revealed that ciprofloxacin performed as well as or better than the standard comparison drugs. . . . The clinical efficacy of these [FLQ] compounds has largely been demonstrated to be equivalent to that of commonly prescribed agents." Ball, P., Chodosh, S., Grossman, R., Tillotson, G., Wilson, R. Causes, Epidemiology, and Treatment of Bronchial Infections, Infect Med. 2000; 17(3).
>
> "The fluoroquinolone group has made a major contribution to the care of infected patients for over 15 years. Recent problems with idiosyncratic, unexpected and serious adverse reactions have affected very small numbers of patients and, whilst leading to the loss of the individual agents concerned, should not raise concerns about the class as a whole without scientific foundation. . . . After treatment of almost 20 million patients with these newer agents, their window of opportunity appears unlikely to be cut short by untimely reports of significant adverse reactions." Ball, P. Adverse drug reactions: implications for the development of fluoroquinolones**.** *Journal of Antimicrobial Chemotherapy* (2003) 51, *Suppl. S1*, 21–27.

224. In fact, when the first major epidemiological study suggesting the permanency of peripheral neuropathy associated with FLQ use was published by Cohen (2001) in the *Annals of Pharmacotherapy*, [redacted], Bayer's director and the co-developer of Cipro and Avelox—quickly sought to downplay the significance of Cohen's findings.[23] It is not coincidental that the publication dates of the industry-driven articles

[23] [redacted]

cited above correspond to the timeframe when FLQs became the most commonly prescribed class of antibiotics to adults in the United States.[24]

225. Thus, Defendants, through the publication of medical literature, deceived potential users and prescribers of FLQ drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects, including permanent peripheral neuropathy.

226. Defendants similarly used promotional practices to deceive potential users and prescribers of FLQ drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects, including permanent peripheral neuropathy. These promotional practices include the J&J Defendants issuing fake "Confidence Court Summons" to hospitals commanding them to appear before the "Confidence Court to answer charges of aiding and abetting results the second or third time, with inconvenience to patients and physicians." The alleged "charges" of wrongdoing included claims that "Levaquin should not be considered the physician's first choice for Bronchitis/Sinusitis" and "that Levaquin should not be considered the workhorse quinolone in the hospital."

227. Defendants also falsely and deceptively kept relevant information from potential FLQ users and minimized prescriber concerns regarding the safety and efficacy of FLQs. For instance, despite learning as early as 1988 (Karlman, et al.) that there was

[24] *See* Linder, JA. et al., Fluoroquinolone prescribing in the United States: 1995 to 2002. *Am J Med.* 2005 Mar;118(3):259-68 ("Fluoroquinolone prescribing increased threefold in outpatient clinics and emergency departments in the United States from 1995 to 2002. Fluoroquinolones became the most commonly prescribed class of antibiotics to adults in 2002.").

reasonable evidence of an association of a serious hazard with its FLQs, Defendants intentionally withheld this information from physicians and patients until September 2004, when the FLQ labeling was finally changed to reflect any risk of developing neuropathy. Even then, however, Defendants sought to minimize the frequency and permanency of these serious events by indicating that they were "rare" and in any event reversible. Defendants knew these labeling statements were false and misleading, because they knew as early as the 1990s that central nervous system-related effects were more common with quinolones than with other antimicrobial classes of drugs and that the onset of events like peripheral neuropathy could be rapid and irreversible. Moreover, as noted above, J&J specifically knew that the label's claim that peripheral neuropathy was "rare" was completely false because they learned in the 1990s through their own postmarketing review that "paraesthesia" (a peripheral nerve injury) was one of the three "most frequently reported AEs" in the U.S. *and* abroad. Defendants continued, through August 2013, to misrepresent in their product labels that cases of neuropathy were "rare."

228. Defendants also continued, through August 2013, to intentionally misrepresent that irreversible neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms. More specifically, until the August 2013 label change, Defendants' FLQ labels specifically stated that the drugs should be "discontinued if the patient experiences symptoms of neuropathy . . . in order to prevent the development of an irreversible condition." This statement is misleading because it implies that permanent peripheral neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms, which, as noted above, is false. Moreover, as noted herein, the current label

for Levaquin remains misleading regarding the risk of developing irreversible peripheral neuropathy following the use of Levaquin.

229. The scientific and medical communities were misled as to the true nature of the risk and benefits of the Defendants' FLQ drugs in particular and in general as to the treatment needs and options for patients in need of antibiotic therapy. It was not until the FLQ label change in August 2013 regarding the rapid onset and potentially permanent nature of neuropathies that the truth began to be generally available in the scientific community. Even then, however, physicians had been so conditioned by the false science published and/or funded for years by Defendants that it was difficult for many of those physicians to accept the truth about the risks and lack of benefits associated with these FLQ drugs. This realization, that FLQ drugs have for years been overprescribed, which is supported by independent studies,[25] has once again prompted the FDA to take action. In November 2015, a FDA subcommittee advisory panel was convened wherein panel members noted that FLQ drugs are overprescribed for common infections when other treatments would work as well with less risk. The advisory panel called on the FDA to strengthen labeling warnings and clarify when FLQ drugs should—and should not—be used.

230. The misconceptions as to the true risks and benefits of Defendants' FLQ drugs were pervasive throughout the medical and scientific communities due to the marketing methods employed by Defendants that included the following:

[25] *See* Lautenbach E, Larosa LA, Kasbekar N, Peng HP, Maniglia RJ, Fishman NO. Fluoroquinolone utilization in the emergency departments of academic medical centers: prevalence of risk factors for inappropriate use. *Arch Intern Med*. 2003;163(5):601–605.

(a) The publication of fraudulent scientific papers in scientific and medical literature;

(b) Providing false and misleading information to doctors during sales and detailing calls at the doctors' offices or at medical or scientific conferences and meetings;

(c) Funding and sponsoring physicians, consultants and/or Key Opinion Leaders to disseminate false and misleading scientific and medical information through medical journals and publications;

(d) Funding third-party companies (including DesignWrite, LLC) to disseminate false and misleading scientific and medical information through its publications and its members to physicians and patients;

(e) Funding continuing medical education to disseminate false and misleading information to doctors;

(f) Paying specialists in the field to meet with prescribing doctors for the purpose of disseminating false and misleading information about the risks and benefits of the FLQ drugs;

(g) Disseminating direct to consumers advertising to drive patients to their doctors' offices to ask for their FLQ drugs based on false and misleading information regarding the risks and benefits of the drugs.

231. In particular, Defendants falsely and deceptively misrepresented material facts regarding the safety and effectiveness of FLQ drugs and fraudulently, intentionally, and/or negligently concealed material information, including adverse information,

regarding the safety and effectiveness of their products, including by concealing the following information:

(a) That there was evidence of peripheral paraesthesia associated with FLQ therapy as early as 1988;

(b) That there was evidence demonstrating that FLQs increase the risk of irreversible peripheral neuropathy as early as 1996;

(c) That the J&J Defendants in particular knew in the mid-1990s that cases of paraesthesia were one of the three "most frequently reported AEs" related to the central nervous system.

(d) That the FLQ drugs were not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy;

(e) The severity, frequency, rapid onset, and potentially disabling nature of peripheral neuropathy caused by the FLQ drugs;

(f) The wide range of injuries caused by FLQ drugs to multiple body systems (e.g., musculoskeletal, neuropsychiatric, peripheral nervous system, senses like vision or hearing, skin, and cardiovascular); and

(g) That FLQs should not be used as a first-line therapy to treat infections for which they are not required.

232. The misrepresentations and/or active concealments were perpetuated directly and/or indirectly by Defendants. Moreover, as a result of these efforts it was accepted by the medical and scientific communities that these FLQ drugs had a certain

risk benefit profile that was shown to be completely false by independent studies, case series, J&J's own postmarketing experience, and individual AE reports (including those contained in the FDA AERS).

233. Defendants were in possession of evidence demonstrating that the FLQ drugs caused serious and sometimes debilitating side effects, including permanent peripheral neuropathies. Nevertheless, Defendants continued to market such products by providing false and misleading information with regard to its safety and efficacy to Plaintiffs and Plaintiffs' treating physicians.

234. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiffs, their prescribing physicians, and the healthcare industry generally.

235. Defendants made these false representations with the intent or purpose that Plaintiffs, their prescribing physicians, and the healthcare industry would rely on them, leading to the widespread use of FLQs by Plaintiffs as well as the general public.

236. At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of these facts, Plaintiffs' physicians would not have prescribed and Plaintiffs would not have taken these FLQ drugs.

237. Plaintiffs, their prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of FLQs that Defendants did suppress, conceal, or fail to disclose to Plaintiffs' detriment.

Plaintiffs justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of FLQs. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiffs would indirectly rely on Defendants' misrepresentations and/or active concealment.

238. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiffs ingested the Defendants' FLQ drugs and suffered injuries as set forth herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VII

[Negligent Misrepresentation]

239. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

240. Defendants negligently and/or recklessly misrepresented to Plaintiffs, their prescribing physicians, and the healthcare industry the safety and effectiveness of FLQs and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by FLQ drugs.

241. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that FLQs had defects, dangers, and characteristics that were other than what

Defendants had represented to Plaintiffs, Plaintiffs' physicians and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiffs, their prescribing physicians, the health care industry, and the consuming public that:

(a) That there was evidence (e.g., Karlman, et al.) of peripheral paraesthesia associated with FLQ therapy (ciprofloxacin) as early as 1988;

(b) That there was evidence (e.g., Hedenmalm, et al.) demonstrating that FLQs increase the risk of irreversible peripheral neuropathy as early as 1996;

(c) That the J&J Defendants in particular knew in the mid-1990s that cases of paraesthesia were one of the three "most frequently reported AEs" related to the central nervous system.

(d) That the FLQ drugs were not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy;

(e) The severity, frequency, rapid onset, and potentially disabling nature of peripheral neuropathy caused by the FLQ drugs;

(f) The wide range of injuries caused by FLQ drugs to multiple body systems (e.g., musculoskeletal, neuropsychiatric, peripheral nervous system, senses like vision or hearing, skin, and cardiovascular); and

(g) That FLQs should not be used as a first-line therapy for minor or uncomplicated infections.

242. The negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

243. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiffs, their prescribing physicians, and the healthcare industry.

244. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiffs, their prescribing physicians, and the healthcare industry would rely on them, leading to the use of FLQs by Plaintiffs as well as the general public.

245. At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had Plaintiffs been aware of said facts, their physicians would not have prescribed and Plaintiffs would not have taken the FLQ drugs.

246. Plaintiffs justifiably relied on and/or were induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Defendants' FLQ drugs and relied on the absence of information regarding the dangers of these drugs which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiffs' detriment.

247. Defendants had a post-sale duty to warn Plaintiffs, their prescribing physicians, and the general public about the potential risks and complications associated with their FLQ drugs in a timely manner.

248. Defendants made the representations and actively concealed information about the defects and dangers of their FLQ drugs with the absence of due care such that Plaintiffs' prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting these FLQs as a treatment.

249. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, Plaintiffs ingested Defendants' FLQ drugs and suffered injuries as set forth herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VIII

[Fraudulent Concealment]

250. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

251. Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed their wrongful conduct from the Plaintiffs with the intent that Plaintiffs and their prescribing physicians would rely on such material representations**.** First, Defendants had actual knowledge of the defective and dangerous

nature of the FLQ drugs. Second, Defendants failed to conduct adequate testing on their FLQ drugs to establish safety and efficacy. Third, Defendants had actual knowledge of their misrepresentations, negligence, breach of warranties, and false, misleading, deceptive, and unconscionable conduct. Yet, Defendants continued to perpetuate their wrongful conduct with the intent and fixed purpose of concealing their wrongs from the Plaintiffs and the public at large.

252. Plaintiffs and their prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Plaintiffs were injured as a direct and proximate result.

253. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiffs, their prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiffs and their prescribing physicians would rely on Defendants' misrepresentations. Plaintiffs and their prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiffs were injured as a result.

254. Defendants, as the manufacturer and/or distributor of their FLQ drugs, were in a position of superior knowledge and judgment regarding any potential risks associated with their drugs.

255. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiffs relating to the FLQ drugs at issue in this lawsuit, said

breach or breaches constituting fraud because of its propensity to deceive others or constitute an injury to public interests or public policy.

256. In breaching their duties to Plaintiffs, Defendants used their position of trust as the manufacturer and/or distributor of FLQ drugs to increase sales of the drugs at the expense of informing Plaintiffs that, by ingesting these drugs, they were placing themselves at a significantly-increased risk of developing irreversible peripheral neuropathy and/or injuries to multiple other body systems (e.g., musculoskeletal, neuropsychiatric, senses like vision or hearing, skin, and cardiovascular).

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IX

[Violation of Consumer Protection Laws/Consumer Fraud Laws]

257. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

258. Plaintiffs plead this Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies to this case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

259. Plaintiffs used Defendants' FLQ drugs and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

260. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

(a) Representing that goods or services have characteristics, ingredients, uses,

benefits, or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

261. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of their FLQ drugs.

262. Defendants violated consumer protection laws of various states.

263. Defendants uniformly communicated the purported benefits of their FLQ drugs while failing to disclose the serious and dangerous side effects related to the use of FLQs and of the true state of FLQs' safety, efficacy, and usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as Plaintiffs, in the marketing and advertising campaign described herein.

264. Defendants' conduct in connection with their FLQ drugs were also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively

misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of FLQs.

265. As a result of these violations of consumer protection laws, Plaintiffs have incurred and will incur serious physical injury (including in some cases death), pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT X

[Loss of Consortium]

266. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

267. Plaintiffs plead this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiffs' resident state.

268. At all relevant times hereto, where applicable, Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of the Plaintiffs' injuries from Defendants' FLQ drugs.

269. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

270. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

271. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

272. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

273. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs, and/or intimate partners of the aforesaid Plaintiffs, have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners are entitled by law.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XI

[Wrongful Death]

274. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

275. Plaintiffs plead this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiffs' resident states.

276. Plaintiffs bring this claim, where appropriate, on behalf of the Estate and for the benefit of the Plaintiff-Decedents' lawful beneficiaries.

277. As a direct and proximate result of the conduct of the Defendants and the defective nature of Defendants' FLQ drugs as outlined above, Plaintiff-Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

278. As a direct and proximate cause of the conduct of Defendants, Plaintiff-Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths. Plaintiffs bring this claim on

behalf of Decedents' lawful beneficiaries for these damages and for all pecuniary losses under applicable state statutory and/or common laws.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XII

[Survival Action]

279. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

280. Plaintiffs plead this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiffs' resident states.

281. As a direct and proximate result of the conduct of Defendants, where appropriate, Plaintiff-Decedents, prior to their death, were obligated to spend various sums of money to treat his or her injuries, which debts have been assumed by the Estate. As a direct and proximate cause of the aforesaid, Decedents were caused pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of his or her death; and, as a direct and proximate result of the aforesaid, Decedents suffered a loss of earnings and earning capacity. Plaintiffs bring this claim on behalf of Decedents' estates under applicable state statutory and/or common laws.

282. As a direct and proximate result of the conduct of Defendants, Plaintiff-Decedents and their spouses and heirs, including domestic partners, until the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder.

283. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Plaintiff-Decedents until the date of their deaths, Plaintiffs have and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Plaintiffs' spouses or heirs, including domestic partners, as Administrators or beneficiaries of the estate of the Decedent, bring the claim on behalf of the estate for damages under applicable statutory and/or common laws, and in their own right.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

PUNITIVE DAMAGES

284. At all times material hereto, Defendants knew or should have known that their FLQ drugs were inherently dangerous with respect to the risk of irreversible peripheral neuropathy.

285. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their FLQ drugs.

286. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety of the FLQ drugs.

287. At all times material hereto, Defendants knew and recklessly disregarded the fact that their FLQ drugs cause the chronic disease of irreversible peripheral neuropathy and/or injuries to multiple other body systems.

288. Notwithstanding the foregoing, Defendants continued to aggressively market their FLQ drugs to consumers, including Plaintiffs herein, without disclosing the aforesaid side effect.

289. Defendants knew of their FLQ drug's lack of warnings regarding the risk of developing irreversible peripheral neuropathy and/or injuries to multiple other body systems, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell their FLQ drugs without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable harm caused by their FLQ drugs.

290. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using FLQs against their benefits.

291. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiffs suffered severe and permanent physical and emotional injuries,

including, but not limited to, irreversible peripheral neuropathy and/or injuries to multiple other body systems. Plaintiffs have endured pain and suffering, have suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiffs' injuries and damages are prolonged and/or permanent and will continue into the future.

292. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

RELIEF REQUESTED

WHEREFORE, Plaintiffs pray for relief and judgment against Defendants and McKesson as follows:

(a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiffs paid for Defendants' FLQ drugs;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

(h) For attorneys' fees, expenses, and costs of this action; and

(i) For such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

DATED: April 22, 2016

Respectfully submitted,

/s/ Russell W. Budd

Russell W. Budd, Esq.
BARON & BUDD, P.C.
3102 Oak Lawn Ave., Suite 1100
Dallas, Texas 75219
Telephone: (214) 521-3605
Facsimile: (214) 520-1181
Email: rbudd@baronbudd.com

Bill Robins III
HEARD ROBINS CLOUD LLP
808 Wilshire Blvd., Suite 450
Santa Monica, CA 90401
Phone: (310) 929-4200
Fax: (310) 566-5900
Email: robins@heardrobins.com

Plaintiffs' Co-Lead Counsel